TENNESSEE DIVISION OF RADIOLOGICAL HEALTH

MEDICAL LICENSE APPLICATION GUIDE

October 2003

The following paragraphs explain the information requested on Form RHS 8-5 "Application for Radioactive Material License." SRPAR is the acronym for "State Regulations for Protection Against Radiation." SRPAR is available for review at http://www.state.tn.us/sos/rules/1200/1200-02/1200-02.htm.

Item 1.a. Enter the name, mailing address, and telephone number of the applicant as they are authorized to do business in Tennessee.

Item 1.b. List the street addresses of locations where radioactive material will be used or stored if other than the address stated in Item 1.a. If multiple addresses are to be used, explain the extent of use at each address and the facilities and equipment located at each place of use.

A license that authorizes more than one address where licensed material is used or stored is assessed at a higher fee than a single site license. It may be financially advantageous to apply for a separate license for each site. Different addresses that are part of the same contiguous facility may be judged as a single site by the Department.

If applying for a license for mobile medical services, submit information requested in Appendix S.

Item 2. Enter the Department to use radioactive material.

Item 3. Indicate if this is an application for a license renewal and give number.

Item 4. List the full names of all physicians who will use or directly supervise the use of licensed material. These are the physicians who use licensed material directly or who are direct supervisors of physicians, technicians, technologists, or other paramedical personnel to whom specific activities are delegated. These physicians must meet the training and experience requirements in SRPAR 1200-2-10-.33 and be named as authorized users on the license. Physicians who only interpret diagnostic scans/studies or the results of therapeutic procedures involving the administration of licensed material to individuals do not need to meet the training and experience requirements of SRPAR, and are not required to be named as authorized users on the license.

Physicians under direct supervision of the named users may be delegated the following responsibilities.

a. The approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from radioisotope sources.

b. The prescription of the radiopharmaceutical or source of radiation and the dose or exposure to be administered.

c. The determination of the route of administration.

Properly trained technicians, technologists, or other paramedical personnel under an authorized user's supervision may be delegated the following activities:

a. Preparation and quality control of radiopharmaceuticals and sources of radiation.

b. Measurement of radiopharmaceutical doses prior to administration.

c. Use of appropriate instrumentation for the collection of data to be used by the physician.

d. Administration of radiopharmaceuticals and radiation from radioisotope sources to patients, within limits otherwise permitted under applicable Federal, State, or local laws.

Item 5. State the name and title of the person designated by, and responsible to, the proposed licensee's management for the day-to-day oversight and coordination of the radiation safety program. If not a full-time employee of the licensed facility, this person shall be on site periodically to conduct person-to-person interactions with licensed staff. If available, provide the email address of the Radiation Safety Officer or other person responsible for the radiation safety program.

Item 6.a. For routine human use the applicant may select the Group Numbers of radioactive materials as found in Appendix A. Groups I, II, and III consist of the more commonly used diagnostic procedures that involve radiopharmaceuticals; Groups IV and V consist of routine therapeutic procedures that involve radiopharmaceuticals; and Group VI consists of sealed sources used primarily for therapeutic procedures.

For Groups I, II, III, maximum possession limits are not listed on the license. The total possession limit for Groups IV and V must be specified. State the requested possession limit for the individual items in Group VI for which you wish to be licensed. A separate application must be submitted for the use of Cobalt 60 sealed sources for teletherapy. Any other radioactive material not included in any of the groups should be listed separately with corresponding possession limits. The possession limit for each radionuclide includes material held as radioactive waste.

Note that a radiopharmaceutical approved by the FDA since the development of these groups may now be a member of a group without being specifically named in SRPAR.

Item 6.b. For routine human use not listed in Groups I through V, and for non-human use, list each radionuclide to be used, the chemical and/or physical form, and the maximum quantity (in millicuries).

List the isotopes needed for all calibration and reference standards. [Sealed sources up to 3 mCi used for calibration and reference standards are authorized under SRPAR 1200-2-10-.14(3)(d) and should not be listed.]

Item 7. Describe the intended use for each radionuclide and form listed in Item 6. If the radioactive material has not been approved for routine human use by the Food and Drug Administration, (FDA), you must use it in accordance with a "Notice of Claimed Investigational Exemption for a New Drug" (IND), a Product License Application (PLA), or other mechanism accepted by the FDA. Certain radioactive materials may be authorized under the rules of Pharmacy.

Items 8. and 9. Training and Experience. Provide information as requested below rather than completing Items 8 and 9 on the license application.

a. Authorized User(s). If the physician has been previously authorized to use the radioactive material requested in this application, it is necessary to submit only the previous license number (if issued by the State of Tennessee) or a copy of the license (if issued by the Nuclear Regulatory Commission or another Agreement State).

SRPAR 1200-2-10-.33 also lists certifications and experience that may be used to qualify for approval as an authorized user of certain radioactive materials. See Appendix B. The Division will also accept additional certifications as follows, any one of which may be used to qualify:

If the physician has not been previously authorized to use the radioactive material being requested, confirm he/she is licensed to practice medicine in Tennessee, and submit a complete description of his/her training and experience. Use Form RHS 8-5A, Pages 1 and 2, Human Medical Use, for the description of the physician's training and experience. Criteria for acceptable training and experience are contained in Appendix B.

Physicians may be named as authorized users for nuclear cardiology if they submit evidence of at least 40 hours of didactic training in applicable radiation principles, and clinical experience under a preceptor physician that documents at least 100 total cases of the various nuclear cardiology studies. To be named as an authorized user for lymphoscintography, the physician should submit evidence of 24 hours of applicable didactic training, and 10 clinical cases under a preceptor physician. The statements of clinical experience must be signed by the preceptor physician.

For Groups I, II and III:

- Certified in Nuclear Medicine by the American Board of Nuclear Medicine
- Certified in Diagnostic Radiology or Radiology by the American Board of Radiology
- Certified in Diagnostic Radiology or Radiology by the American Osteopathic Board of Radiology
- Certified in Nuclear Medicine by the Royal College of Physicians and Surgeons of Canada
- Certified in Nuclear Medicine by the American Osteopathic Board of Nuclear Medicine

For Groups IV and V:

- Certified by the American Board of Nuclear Medicine in Nuclear Medicine
- Certified by the American Board of Radiology in Radiology, Therapeutic Radiology, or Radiation Oncology
- Certified by the Royal College of Physicians and Surgeons in Nuclear Medicine
- Certified by the American Osteopathic Board of Radiology after 1984

For Group VI:

- Certified by the American Board of Radiology in Radiology, Therapeutic Radiology, or Radiation Oncology

- Certified by the American Osteopathic Board of Radiology in Radiation Oncology
- Certified in Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of College of Radiology"
- Certified by the Canadian Royal College of Physicians and Surgeons in Therapeutic Radiology

For Nuclear Cardiology:

- Certified by the Certification Board of Nuclear Cardiology

b. Radiation Safety Officer. If the radiation safety officer is not one of the physicians named in Item 4, submit a complete description of his/her training and experience.

Item 10. Instrumentation. Instruments required for a typical human use license are listed below. Confirm that you will have:

a. Survey Instruments

(1) A survey meter with a thin window probe capable of detecting 0.1 mr/hr to perform contamination surveys and capable of reading up to 200 mr/hr to measure radiation exposure rates.

(2) For those wishing to dispose of empty radioactive material containers, or materials, items, etc., once contaminated with radioactive isotopes, to the normal trash, a survey meter capable of detecting 0.02 mr/hr to measure at background levels.

b. Dose calibrators or other instruments to assay radiopharmaceuticals.

Item 11. Calibration of Instruments

a. Survey Instruments. An adequate calibration of survey instruments cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument.

Daily constancy checks of survey instruments should be supplemented at least every 12 months with a battery check and two-point calibration on each scale of the instrument. These points should be approximately $^{1}/_{3}$ and $^{2}/_{3}$ of full scale. Survey instruments should also be calibrated after repair.

A survey instrument may be considered properly calibrated at one point when the exposure rate measured by the instrument differs from the true exposure rate by less than 20% of full scale.

If you propose to calibrate your own radiation survey and monitoring instruments, submit a detailed description of your planned calibration procedures. Include in the description:

(1) The manufacturer's name and model number of the source(s) to be used.

(2) The nuclide and activity (in millicuries) of radioactive material contained in the source.

(3) The accuracy of the source(s).

(4) The step-by-step procedures, including associated radiation safety procedures. These procedures should include a two-point calibration of each scale of each instrument. These points should be approximately 1/3 and 2/3 of full scale.

If a consultant or outside firm will perform the calibration of your radiation survey and monitoring instruments, confirm that radiation monitoring instruments will be calibrated by a person authorized by the Nuclear Regulatory Commission or an Agreement State to perform survey meter calibrations.

*Appendix C.1 to this Guide contains an acceptable procedure for calibrating survey meters and Appendix C.2 contains a form that should be used to supply the information required in Item 11 of the application form. Indicate that the procedures contained in Appendix **C.1** will be followed or submit equivalent procedures.*

b. Equipment Used To Measure Doses All radiopharmaceuticals should be assayed for activity to an accuracy of 20% prior to being administered to patients. The usual method for performing assays is with a dose calibrator. Upon installation, after repair, and periodically thereafter, dose calibrators shall be tested for accuracy of response for the energies commonly used, for geometrical variation, for linearity of response over the entire range of activities to be used, and for constancy and proper operation at the beginning of each day of use. These tests shall be made in accordance with Appendix C.3 (referenced below), American National Standards Institute standards [ANSI N42.13-1986 (R1993)], or the manufacturer's procedures, and shall be maintained for inspection by the Department.

Appendix C.3 to this Guide contains a description of an acceptable procedure for calibrating dose calibrators. Indicate that the procedures contained in Appendix C.3 are followed or submit equivalent procedures.

Item 12. Personnel Dosimetry

SRPAR 1200-2-5.-.71 requires that occupational exposures to radiation be monitored for individuals who are likely to receive an external dose or intake of radioactive material in excess of certain levels. Records of personnel monitoring are required to be maintained. You may evaluate the exposure of occupational workers to determine if personnel monitoring is required. These evaluations should be maintained to justify any determinations made.

Confirm that personnel monitors, except for extremity monitors and pocket ionization chambers, shall be processed and evaluated by a dosimetry processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP). NVLAP may be reviewed at http://ts.nist.gov/ts/htdocs/210/214/scopes/programs.htm.

If it is necessary to monitor the intake of radioactive material, the licensee may use Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program." Regulatory Guide 8.9 may be reviewed at http://www.nrc.gov/reading-rm/doc-collections/reg-guides/occupational-health/active/8-09.

Item 13. Facilities and Equipment

Submit a diagram with access points of all room(s) where radioactive material is used and/or stored including surrounding areas. Also, include in this diagram a description of the area(s) assigned for the receipt, storage (including waste), preparation, administration, and measurement of radioactive material.

This does not include patient rooms where radiopharmaceuticals are used. Describe any facility or portable shielding that may be necessary in order for the licensee to be able to conduct operations so that the annual dose limit to the public as required by SRPAR 1200-2-5-.60 is not exceeded. This may be most appropriate for Positron Emission Tomography, High Dose Rate Afterloader (HDR), or certain therapy operations.

Describe the safety equipment to be employed in the use of licensed material. For nuclear medicine this shall include shielding for storage, shielding for preparation (L-block), syringe shields, transport shields, shielding for waste, Xenon dispenser, Xenon trap, and fume hood, if applicable. For brachytherapy this shall include shielding for storage (shielded safe required for Cs-137), shielding for preparation (L-block), transport shields, and portable shields for patients. For HDR this shall also include the interlock and alarm system.

For facilities in which radioactive material may become airborne, e.g., Xenon 133, Appendix L to this guide contains an acceptable set of rules for the safe use of these radioactive materials. Indicate if Appendix L rules will be followed, or attach equivalent procedures.

Item 14. Radiation Protection Program

1. Radiation Safety Committee In accordance with 1200-2-10-.13(1)(a) of "State Regulations for Protection Against Radiation," an institution applying for a radioactive material license for human use is required to establish a radiation safety committee to oversee the use of licensed material throughout the institution and to review the institution's radiation safety program. Membership of the committee must include:

    a. An authorized user for each type of use permitted by the license.

    b. A representative of the nursing staff.

    c. A representative of the institution's management.

    d. The Radiation Safety Officer.

Submit the following information:

    a. The duties of the committee.

    b. The meeting frequency of the committee (at least quarterly).

    c. Minutes of the meetings will be maintained.

Appendix D to this Guide contains an example of typical responsibilities and duties for a Radiation Safety Committee. If the responsibilities, duties, or meeting frequency of your committee will be essentially the same as those described in Appendix D, submit a copy of Appendix D. This form may be altered to appropriately describe your committee.

Please note that for private practice operations or for those programs authorized for a single use of radioactive material, a radiation safety committee is not required.

2. Personnel Training Program Describe the training required for all personnel who work with or in the vicinity of radioactive materials. Include the form of training (e.g., formal course work, lectures), frequency of training, duration of training, and subject matter. The training program should be of

sufficient scope to ensure that all personnel, including technical, clerical, nursing, housekeeping, and security personnel, receive proper instruction in the items that follow:

a. Areas where radioactive material is used or stored.

b. Potential hazards associated with radioactive material.

c. Radiological safety procedures appropriate to their respective duties.

d. Pertinent State Regulations.

e. Conditions of the licensee.

f. Pertinent terms of the licensee.

g. Their obligation to report unsafe conditions.

h. Appropriate response to emergencies or unsafe conditions.

i. Their right to be informed of their radiation exposure and bioassay results.

j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 1200-2-4-.11(1) of SRPAR.

Verify that personnel will be properly instructed:

a. Before assuming duties with or in the vicinity of radioactive materials.

b. During annual refresher training.

c. Whenever there is a significant change in duties, regulations, or the terms of the license.

3. Procedures for Safely Opening Packages In Which Radioactive Material Is Received, and Receipt of Packages Submit procedures for examining incoming packages for leakage, contamination, or damage, and for safely opening packages in accordance with SRPAR 1200-2-5-.115(5). The procedures may vary depending on the quantity of radioactive material received but should, at a minimum, include instructions for surveying packages, wearing gloves while opening packages, and checking packing material for contamination after opening.

Appendix E to this guide contains acceptable procedures for ordering and receiving radioactive material. Appendix F to this guide contains acceptable procedures for safely opening packages containing radioactive material. Indicate that the procedures in Appendices E and F will be followed, or attach equivalent procedures.

4. Safety Rules Appendix G to this guide contains an acceptable set of rules for the safe use of radioactive material. Indicate if Appendix G rules will be followed, or attach equivalent procedures.

5. Leak Tests of Sealed Sources Submit sealed source leak testing and analysis procedures if you wish to be authorized to perform leak tests for your licensed sealed sources. If not, confirm that sealed source leak tests will be analyzed by persons authorized by the Nuclear Regulatory Commission or an Agreement State.

6. Emergency Procedures Describe the emergency instructions to be posted in all areas where radioactive materials are used. These instructions should (a) describe immediate action to be taken in order to prevent contamination of personnel and work areas (e.g., turning off the ventilation, evacuation of the area containment of the spill), (b) state the names and telephone numbers of the responsible persons to be notified in case of an emergency, and (c) instruct personnel on appropriate methods for re-entering, decontaminating, and recovering facilities that may have been accidentally contaminated.

An acceptable set of emergency procedures is contained in Appendix H to this Guide. Indicate that emergency procedures in Appendix H will be followed or submit a copy of equivalent procedures with your application.

7. Area Survey Procedures Describe the routine survey program, including the areas to be surveyed, the levels of contamination considered to be acceptable, and provision for maintaining records of surveys.

Acceptable procedures and frequencies for routine surveys are described in Appendix I to this guide. Indicate that you will follow the survey procedures in Appendix I or submit equivalent procedures.

8. Therapeutic Use of Radiopharmaceuticals Describe special precautions for patients treated with byproduct material listed in Groups IV and V.

Although Group IV procedures are often performed on an outpatient basis, hospitalization is sometimes required. If procedures are to be performed only on an outpatient basis, please specify and submit only the applicable procedures. Appendix O to this guide contains acceptable procedures for the release of patient administered radioactive materials. Indicate that the procedures in Appendix O will be followed, or attach equivalent procedures.

If patients are to be hospitalized, establish appropriate procedures for all patients treated with licensed material and include:

a. Method for preparation and administration of therapeutic doses of Iodine 131. This would include a commitment to open containers of liquid Iodine 131 in a containment system with adequate airflow to prevent contamination of themselves and surrounding areas.

b. Significant thyroid uptakes have been detected in individuals who open and prepare oral solutions of Iodine 131 for therapeutic doses. The use of capsules does not normally require bioassay of personnel except for a crushed capsule, etc. In these situations, a bioassay may be necessary. A bioassay is a determination of the kind, quantity or concentration, and location of radioactive material in the human body. In the case of iodine, this would involve in vivo measurement of the gamma radiation emitted from the thyroid gland, or in vivo analysis of the iodine present in a urine sample. If it is necessary to monitor the intake of radioactive material, the licensee may use Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program." Regulatory Guide 8.9 may be reviewed at http://www.nrc.gov/reading-rm/doc-collections/reg-guides/occupational-health/active/8-09.

Appendix J to this guide contains a description of precautions to be followed for patients, treated with Groups IV and V radiopharmaceuticals. Indicate that you will follow Appendix J procedures, or submit equivalent procedures.

9. Therapeutic Use of Sealed Sources Describe special procedures for patients treated with byproduct materials listed in Group VI.

   These procedures should include descriptions of:

   a. The areas where sealed sources will be stored, including (1) placement and thickness of shielding, and (2) proximity of the storage area to unrestricted areas.

   b. Special precautions to be used while handling sealed sources.

   c. Your method for determining the radiation doses to the extremities of personnel handling sealed sources.

   d. The equipment and shielding available for transporting sources from storage sites to the place of use.

   e. Your method for maintaining source accountability at all times. This should include a description of sign-in and sign-out procedures, periodic inventory, and the method for determining that all sources are accounted for and returned to storage following treatment.

   f. Surveys to be performed during the course of treatment and at the conclusion of treatment. The patient and room should be surveyed with a radiation survey instrument after the end of treatment and before dismissal. Your dismissal survey should include a source count and should be adequate to determine that all temporary implant sources have been removed from the patient and from all areas that the patient occupied.

Special instructions for nursing care of patient who are treated with sealed sources. Appendix K to this guide contains a description of procedures to be followed for patients treated with sealed sources. Indicate that you will follow Appendix K procedures or submit equivalent procedures.

Appendix O to this guide contains an acceptable procedures for the release of patient administered these radioactive materials. Indicate Appendix O procedures will be followed or attach equivalent procedures:

Please note that if procedures are specific to Intravascular Brachytherapy, High Dose Rate Brachytherapy, or the use of Group VI sealed sources of Low Energy (Pd 103/I-125), refer to Appendices P through Q, respectively.

10. Procedures and Precautions for Use of Radioactive Gases (e.g., Xenon 133) The use of radioactive gases (e.g., Xenon 133 gas or gas in saline) requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive gas in restricted and unrestricted areas. It is required that each applicant make such determinations for his own unique situation and submit sufficient evidence in support of his request.

Appendix L to this guide contains instructions for submitting an application to use Xenon 133. The information requested in Appendix L must be submitted.

Item 15. Waste Disposal

Describe specific methods used for disposal of waste byproduct material. A licensee may dispose of waste by:

a. Transfer to a person properly licensed by the NRC or Agreement State to receive such waste, e.g., commercial waste disposal firms.

b. Release into a sanitary sewer in conformance with SRPAR 1200-2-5-.122.

c. Release into the air in conformance with SRPAR 1200-2-5-.61.

d. Other methods specifically approved by the Division pursuant to SRPAR 1200-2-5-.121.

Note: No licensee may dispose of byproduct material waste by incineration unless specifically approved by the Division. [See SRPAR 1200-2-5-.123]

Appendix N to this guide contains acceptable procedures for waste disposal. Indicate that you will dispose of wastes as specified in Appendix N or attach equivalent procedures.

Item 16. Signature of Certifying Official

The application should be signed by the Administrator or other appropriate management official. Authorized physician users that are named on the license, or named Radiation Safety Officer may sign on behalf of the Administrator in future license correspondence. Others, including consultants, must be approved by management to sign for the institution. This approval should be submitted in writing to this Department listing the authorized individual or individuals.

AMENDMENT TO LICENSES

Licenses are required to conduct their programs in accordance with statement, representations, and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make any changes in the facilities, equipment, procedures, authorized users or radiation safety officer, or byproduct material to be used.

Requests for license amendments may be submitted in letter form. Requests should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific, and should identify the pertinent information by date, page, and paragraph. An original and two copies of the request for amendment should be prepared; the original and one copy should be submitted, as in the cases for new or renewal applications.

LIST OF APPENDICES

APPENDIX A

GROUPS OF MEDICAL USES OF RADIOACTIVE MATERIAL [SRPAR 1200-2-10-.14(6)]

1. Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurement of uptake, dilution, and excretion. This group does not include uses involving imaging and tumor localizations.

   A. Iodine 123 as sodium iodide;

   B. Iodine 125 as sodium iodide, iodinated human serum albumin, oleic acid, or sodium iothalamate;

   C. Iodine 131 as sodium iodide, iodinated human serum albumin, labeled rose bengal, triolein, or sodium iodohippurate;

   D. Cobalt 57 as labeled cyanocobalamin;

   E. Cobalt 58 as labeled cyanocobalamin;

   F. Cobalt 60 as labeled cyanocobalamin;

   G. Chromium 51 as sodium chromate or labeled human serum albumin;

   H. Potassium-42 as chloride;

   I. Sodium-24 as chloride;

   J. Iron 59 as citrate;

   K. Technetium 99m as pertechnetate; and

   L. Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the U.S. Food and Drug Administration (FDA).

2. Group II. Use of prepared radiopharmaceuticals for diagnostic imaging and localization studies.

   A. Iodine 131 as sodium iodide, iodinated human serum albumin, macroag-gregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate;

   B. Iodine 125 as sodium iodide or fibrinogen;

   C. Iodine-123 as sodium iodide;

   D. Chromium 51 as human serum albumin;

   E. Fluorine-18 in solution;

F. Gallium-67 as citrate;

G. Gold 198 in colloidal form;

H. Mercury 197 as chlormerodrin;

I. Mercury 203 as chlormerodrin;

J. Selenium 75 as selenomethionine;

K. Strontium 85 as nitrate;

L. Strontium 87m as chloride;

M. Technetium 99m as pertechnetate, sulfur colloid, or macroaggregated human serum albumin;

N. Thallium-201 as chloride;

O. Ytterbium 169 as pentatate sodium;

P. Indium 113 as chloride;

Q. Any radiopharmaceutical prepared from a reagent kit, listed in (c)3. of this paragraph; and

R. Any radioactive material in a radiopharmaceutical and for a diagnostic use involving imaging or localizing for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the U.S. Food and Drug Administration (FDA).

3. Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals for certain diagnostic studies.

A. Molybdenum 99/Technetium 99m generators for the elution of Technetium 99m as pertechnetate;

B. Technetium 99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing Technetium 99m as provided in (c)3 and (c)5 of this subparagraph;

C. Reagent kits for preparation of Technetium 99m labeled:

(1) Sulfur colloid;
(2) Pentatate sodium;
(3) Etidronate sodium;
(4) Human serum albumin;
(5) Human serum albumin microspheres;
(6) Polyphosphates;
(7) Macroaggregated human serum albumin;
(8) Medronate sodium;
(9) Stannous phyrophosphate;
(10) Gluceptate sodium;
(11) Oxidronate sodium;
(12) Disofenin;
(13) Succimer.

D. Tin 113/Indium 113m generators for the elution of Indium 113m as chloride, and

E. Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical for which generator or reagent kit a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the U.S. Food and Drug Administration (FDA).

4. Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety:

A. Iodine 131 as iodide for treatment of hyperthyroidism and cardiac dysfunction;

B. Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases;

C. Phosphorus 32 as colloidal chronic phosphate for intracavitary treatment of malignant effusions;

D. Any radioactive material in a radiopharmaceutical for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the U.S. Food and Drug Administration (FDA).

5. Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety:

A. Gold 198 as colloid for intracavitary treatment of malignant effusions;

B. Iodine 131 as iodide for treatment of thyroid carcinoma;

C. Any radioactive material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the U.S. Food and Drug Administration (FDA).

6. Group VI. Use of sealed sources and devices containing radioactive material for certain medical uses:

A. Americium 241 as a sealed source in a device for bone mineral analysis;

B. Cesium 137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

C. Cobalt 60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

D. Gold 198 as seeds for interstitial treatment of cancer;

E. Iodine 125 as a sealed source in a device for bone mineral analysis;

F. Iridium 192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

G. Strontium 90 sealed in an applicator for treatment of superficial eye condition;

H. Radon 222 as seeds for interstitial treatment of cancer;

I. Radium 226 encased in needles, applicator cells, and plaques for topical, interstitial and intracavitary treatment of cancer; and

J. Iodine 125 as seeds for interstitial treatment of cancer.

APPENDIX B

ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF RADIOACTIVE MATERIAL (SRPAR 1200-2-10-.33)

1. General Training.

   To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Groups I, II, and/or III of Rule 1200-2-10-.14, a physician should have:

   A. Training in basic radioisotope handling techniques consisting of lectures, laboratory sessions, discussion groups of supervised experience in a nuclear medicine laboratory in the following areas (200 hours):

      (1) Radiation physics and instrumentation (approx. 100 hours)

      (2) Radiation Protection (approx. 30 hours)

      (3) Mathematics pertaining to the use and measurement of radioactivity (approx. 20 hours)

      (4) Radiation biology (approx. 20 hours)

      (5) Radiopharmaceutical chemistry (approx. 30 hours)

   B. Experience with types and quantities of radioactive material for which the application is being made, or equivalent (500 hours). For authorization for Group III (generators and reagent kits), this experience should include personal participation in five procedures to elute Tc-99m, including testing of eluate, and five procedures to prepare radiopharmaceuticals from Group III reagent kits.

   C. Supervised clinical training in an institutional nuclear medicine program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and include:

      (1) Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.

      (2) Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data.

      (3) Follow-up of patient when required.

      (4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitations, contraindications, etc.

   D. The requirements specified in subparagraph 1200-2-10-.33(1)(a), (b), and (c) may be satisfied concurrently in a three-month training program IF all three areas are integrated into the program.

   E. In lieu of the requirements in 1200-2-10-.33(1)(a), (b), and (c), certification by the American Board of Nuclear Medicine or the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology will be accepted as evidence that a physician has had adequate training and experience to use Groups I, II, and III.

2. Training Requirements for Specific Diagnostic Procedures.

   For the applicant who wishes to be authorized for only one or two specific diagnostic procedures, the physician named to use or directly supervise the use of radioactive material should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of radioactive material being requested.

3. Training Requirement for Therapy Procedures Involving Radiopharmaceuticals.

   To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Groups IV and/or V of Rule 1200-2-10-.14, a physician should have:

   A. Training in basic radioisotope handling techniques (80 hours) including:

      (1) Radiation physics and instrumentation (approx. 25 hours)

      (2) Radiation protection (approx. 25 hours)

      (3) Mathematics pertaining to the use and measurement of radioactivity (approx. 10 hours)

      (4) Radiation biology (approx. 20 hours)

   B. Clinical training in specific therapy procedures:

      (1) For Group IV

         (a) Iodine 131 for treatment of hyperthyroidism and/or cardiac conditions: Clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten patients.

         (b) Phosphorus 32 for treatment of polycythemia vera, leukemia, and/or bone metastases: Treatment of three patients with any combination of these three conditions.

         (c) Colloidal phosphorus 32 for intracavitary treatment: Active participation in the treatment of three patients.

      (2) For Group V

         (a) Iodine 131 for treatment of thyroid carcinoma: Clinical experience in diagnosis of thyroid function and treatment of hyperthyroidism and/or cardiac dysfunction, and active participation in the treatment of three patients with thyroid carcinoma.

         (b) Colloidal Gold 198 for intracavitary treatment: Active participation in the treatment of three patients.

4. Training Requirement for Therapy Procedures Involving Sealed Sources.

   To qualify as adequately trained to use or directly supervise the use of radioactive material listed in Group VI of Rule 1200-2-10-.14, a physician should have:

A. Training in basic radioisotope handling techniques consisting of lectures, laboratory sessions, discussion groups of supervised experience in the following areas (200 hours):

(1) Radiation physics and instrumentation (approx. 110 hours)

(2) Radiation Protection (approx. 40 hours)

(3) Mathematics pertaining to the use and measurement of radioactivity (approx. 25 hours)

(4) Radiation biology (approx. 25 hours)

B. Experience with the types and quantities of radioactive material for which the application is being made, or equivalent (500 hours). This experience should include:

(1) Review of initial source calibration and periodic spot-check measurements of teletherapy units,

(2) Calibration of ion chambers and survey meters,

(3) Preparation of treatment plans and treatment times,

(4) Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed source, and

(5) Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes.

C. Clinical training shall include active participation in therapeutic radiology with a minimum of 3 years experience of which at least one year should have been spent in a formal training program accredited by the Residency Review Committee of Radiology and the Liaison Committee on Graduate Medical Education. This training must include therapeutic treatment of patients of both sexes, all ages, various organs, etc., using sealed sources.

D. In lieu of the requirement in subparagraphs 1200-2-10-.33(4)(a), (b) and (c) certification by the American Board of Radiology in Radiology or Therapeutic Radiology will be accepted as evidence that a physician has had adequate training and experience to use Group VI.

5. Training for Physicians Wishing to Use Strontium 90 Ophthalmic Eye Applicators *Only*. To qualify as adequately trained to use or supervise the use of a Strontium 90 eye applicator only, a physician should submit:

A. Evidence of certification by the American Board of Radiology in radiology or therapeutic radiology, or

B. Evidence of:

(1) Active practice in therapeutic radiology or ophthalmology, and

(2) Training in basic radioisotope handling techniques, including: (24 hours)

(a) Radiation physics and instrumentation (6 hours)

(b) Radiation protection (6 hours)

(c) Mathematics pertaining to the use and measurement of radioactivity (4 hours)

(d) Radiation biology (8 hours)

(3) Evidence of active participation in the treatment of *five patients* (to be submitted on Preceptor Statement). "Active participation" should include supervised examination of patients, collaboration and calculations concerning the dose to be used, administration of the dose to the patient, and follow-up and study of patient care histories.

APPENDIX C.1

METHODS FOR CALIBRATION OF SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY

1. Calibration of survey meters shall be performed with radionuclide sources.

   A. The sources shall be approximate point sources.

   B. The source activities shall be traceable within 5% accuracy to the U.S. National Bureau of Standards (NBS) calibrations.

   C. The frequency shall be at least annually and following repair.

   D. Each scale of the instrument shall be calibrated at approximately 1/3 and 2/3 of full scale.

   E. The exposure rate measured by the Instrument shall differ from the true exposure rate by less than 20% of full scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration).

NOTE: Sources of Cs-137 or Co-60 are appropriate for the performance of calibration. The activity of the calibration standard should be sufficient to calibrate the survey meters on all ranges, or at least up to 200 mr/hr.

2. A reference check source of long half-life, e.g. Cs-137, shall also be read at the time of the above calibration. The reading shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:

   A. Before each use.

   B. After each maintenance and/or battery change

   C. At least quarterly.

   If any reading with the same geometry is not within ±20% of the reading measured immediately after calibration, the instrument should be recalibrated (see Step 1).

3. Records of 1, 2.B, and 2.C above must be maintained.

4. Use of Inverse Square Law and Radioactive Decay Law

   A. A calibrated source will have a calibration certificate giving its output at a given distance measured on a specified date by the manufacturer or NBS.

      (1) The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

      (2) The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

B. INVERSE SQUARE LAW

Exposure rate at P_2:

$$R_2 = \frac{(P_1)^2}{(P_2)^2 \times R_1}$$

(1) R_1 and R_2 are in the same units (mr/hr or R/hr)

(2) P_1 and P_2 are in the same units (cm, meter, feet, etc.)

C. RADIOACTIVE DECAY LAW:

Exposure rate t units of time after specified calibration date:

$R_t = R_o \times e^{0.693 \times t / T^{1/2}}$

(1) $T^{1/2}$ is radionuclide half-life

(2) t is number time elapse calibration time of units of time between and present time

(3) R_o and R_t are in the units (mr/hr or R/hr):

(4) R_o is exposure rate on specified calibration date

(5) R_t is exposure rate t unit of time later

(6) $T^{1/2}$ and t are in the same units (years, months, days, etc.)

APPENDIX C.2

CALIBRATION OF SURVEY INSTRUMENTS

Check items and provide data as appropriate

_____1. Survey instruments will be calibrated at least annually and following repair.

_____2. Calibration will be performed at two points on each scale. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ±10% of the calculated or known values for each point checked. Readings within ±20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

_____3. Survey instruments will be calibrated

_____a. By the manufacturer

_____b. At the licensee's facility

(1) Calibration source _____
Manufacturer's name Model No. _____
Activity in millicuries Accuracy _____
Traceability to primary standard _____

(2) The calibration procedure contained in Appendix C-1, will be used. Attach a copy of Appendix C.1, appropriately completed as part of your application.

OR

(3) Equivalent procedure is attached.

_____c. By a consultant or outside firm

Name _____

Location _____

Procedures and sources

_____ have been approved by NRC or Agreement State License and are on file in License No. _____ with attached copy.

APPENDIX C.3

METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

All radiopharmaceuticals must he assayed for activity to an accuracy of ten percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

1. Test for the following

   A. Instrument constancy (daily prior to assay of patient doses)

   B. Instrument accuracy (at installation and annually thereafter)

   C. Instrument linearity (at installation and quarterly thereafter)

   D. Geometrical variation (at installation)

2. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above. (Dependent upon the nature of the repairs.)

3. Test for Instrument Constancy

   Instrument constancy means that there is reproducibility within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source, such as Cs-137 or Co-57, using a reproducible geometry before each day's use of the instrument. Preferably, at least one reference source (for example, 3-5 mCi of Co-57 and 100-200 μCi of Cs-137 (with appropriate decay corrections) will be assayed each day of use to test the instrument's performance over a range of photon energies and source activities.

   A. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).

   B. Measure background level at same instrument setting or check that automatic background subtraction is operating properly when blinks arc inserted in the calibrator.

   C. Calculate net activity of each source subtracting out background level.

   D. For each source, plot net activity versus the day of the year on semilog graph paper.

   E. Log the background levels.

   F. Indicate the predicted activity of each source based on decay calculations and the ±10 percent limits on the graph.

   G. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.

   H. Variations greater than ±10 percent from the predicted activity indicate the need for instrument repair or adjustment.

   I. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

4. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set. (See manufacturer's instructions)

5. Test of Instrument Linearity

   The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

   A. Assay the Tc-99m vial in the dose calibrator and subtract background level to obtain net activity in millicuries.

   B. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.

   C. Using the 30-hour activity measurement as a starting point calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay, Time (hr)*	*Correction Factor*
0	31.633
6	15.853
24	1.995
30	1
48	0.126

   Example: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be 15.625 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

   D. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).

   E. The activities plotted should be within ±10 percent of the calculated activity it the instrument is linear and functioning properly. Errors greater than ±10 percent indicate the need for repair or adjustment of the instrument.

   F. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.

   G. The licensee may choose to use a shield method for performance of instrument linearity. If the licensee chooses this method, a copy of the manufacturer's procedures shall be maintained for inspection by the Department.

*Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

6. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ±10 percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

A. Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.

B. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

C. Select one volume as a standard (such as the volume of reference standard used in performing the test (or instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected.

4 ml Volume CF = 2.00 2.04 = 0.98

D. Plot the correction factors against the volume oil linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

E. The true activity of a sample is calculated as follows:

True Activity = Measured Activity x Correction Factor

where the correction factor used is for the same volume and geometrical configuration as the sample measured.

F. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.

G. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower- energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction it significant).

7. Test for Instrument Accuracy

Check the accuracy of the dose calibrator with a source(s) which energy falls between 100 and 500 KeV, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources flat have been assayed by NBS and documented.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

A. Assay the reference standard in the dose calibrator at the appropriate selling, and subtract the background level to obtain the net activity.

B. Repeat step 1 for a total of 3 determinations, and average results.

C. The average activity determined in step 2 should agree with the certified activity of the reference source within ±10 percent after decay corrections.

D. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

E. Keep a log of these calibration checks.

F. Calibration checks that do not agree within ±10 percent indicate that the instrument should be repaired or adjusted. It this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

G. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

APPENDIX D

RADIATION SAFETY COMMITTEE

Responsibility

The committee is responsible for

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with State regulations and the conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with State regulations and the conditions of the license.

Duties

The committee shall

1. Be familiar with all pertinent State regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with State regulations and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by SRPAR 1200-2-4-.12.

4. Review and approve all results for use of radioactive material within the institution.

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with State regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of State inspection, written safety procedures, and management control system.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records recommendations, and decisions of all committee meetings, actions, recommendations, and decisions.

9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

Meeting Frequency

The Radiation Safety Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

APPENDIX E

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. During normal working hours carriers will be instructed to deliver radioactive material packages directly to the Nuclear Medicine Department.

2. For packages delivered after normal working hours, you must develop and submit procedures in accordance with the procedures outlined in attached memorandum.

MEMORANDUM FOR: Security Personnel

FROM: _____, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive before or after normal working hours, or on Sundays, shall be signed for by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: _____

OFFICE PHONE: _____

HOME PHONE: _____

APPENDIX F

PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted stop procedure and notify Radiation Safety Officer.

2. Put on gloves.

3. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slips, and label on bottle) check integrity of final source container (inspect for breakage of seals or vials, loss of liquid, discoloration of packing material). Check also that shipment does not exceed possession limits.

4. If there is any reason to suspect external contamination, wipe external surface of final source container with moistened cotton swab or filter paper held with forceps, assay, and record.

5. Monitor the packing material and packages for contamination before discarding:

   A. If contaminated, treat as radioactive waste.

   B. If not, obliterate radiation labels before discarding in regular trash.

Monitoring limits and requirements for received packages are outlined in SRPAR 1200-2-5-.115(2) and 1200-2-5-.115(3).

APPENDIX G

RULES FOR THE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats, or other protective clothing at all times in areas where radioactive material are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances, such as pediatric cases, where their use would compromise the patient's well-being.

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 20%.

7. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist level.

8. Wear finger badges during elution of generator and preparation, assay, injection of radiopharmaceuticals, or handling of brachytherapy sources.

9. Dispose of radioactive waste only in specially designated receptacles.

10. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

11. Confine radioactive solutions in covered containers plainly identified an labeled with name of compound, radionuclide, date, activity, and radiation level if applicable.

12. Always transport radioactive material in shielded containers.

APPENDIX H

EMERGENCY PROCEDURES

MINOR SPILLS

1. NOTIFY: Notify persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

MAJOR SPILLS

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: _____

EMERGENCY CONTACT NUMBER: _____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RSO:

_____

_____

_____

APPENDIX I

SURVEY PROCEDURES

1. Perform periodic surveys of ambient radiation dose rates in unrestricted and restricted areas as needed to ensure that regulatory dose limits to the public and occupational workers are met. Trigger levels for investigation and response shall be 0.1 mr/hr and 5 mr/hr for unrestricted and restricted areas, respectively.

2. All radiopharmaceutical elution, preparation, assay, and patient administration areas will be surveyed at the end of each day for contamination with a G-M survey meter and decontaminated if necessary. Patient rooms where diagnostic administrations are made need not be surveyed if special care is taken to remove all potentially contaminated items and no contamination is suspected.

3. Patient radiopharmaceutical therapy rooms shall be surveyed for ambient radiation levels and contamination at the end of therapy.

4. Laboratory areas where only small quantities of radioactive material are used (less than 200 µCi) will be surveyed monthly for contamination.

5. Radionuclide storage and radioactive waste storage areas will be surveyed weekly for contamination.

6. Sealed source and brachytherapy source storage areas shall be surveyed quarterly for ambient radiation dose rates.

7. The surveys in Items 1 through 6 will consist of a measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mr/hr and capable of measuring dose rates of 200 mr/hr.

8. Surveys in Items 3 through 5 shall include a series of smear tests to measure removable contamination levels. The method for performing smear tests will be sufficiently sensitive to detect 1000 dpm/100 cm^2 for beta-gamma radionuclides and 200 dpm/100 cm^2 for radiodine. To meet these criteria, it is acceptable to use a GM counter with a thin end-window or pancake probe to determine that smears do not exceed the instrument background level as measured in a low background area on the most sensitive scale.

   Removable surface contamination trigger levels for decontamination of restricted areas are 2,000 dpm/100 cm^2 for beta-gamma radionuclides except for only Technetium 99m, Thallium 201, Gallium 67, Mercury 197, Cobalt 57, and Chromium 51 only which are 20,000 dpm/100 cm^2.

   Trigger levels for unrestricted areas are 1000 dpm/100 cm^2 for beta-gamma radionuclides and 200 dpm/100 cm^2 for radioiodine.

9. A permanent record will be kept of all survey results, including negative results. The record will include:

   A. Location, date, and type of survey equipment used.

   B. Name of person conducting the survey.

   C. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   D. Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).

   E. Detected contamination levels keyed to location on drawing.

   F. Corrective action taken in the case of contamination or excessive exposure rates, reduced contaminated levels, or exposure rates after corrective action, and any appropriate comments.

APPENDIX J

PROCEDURES FOR HOSPITALIZATION OF RADIOPHARMACEUTICAL THERAPY PATIENTS (GROUPS IV & V)

1. All in-patients treated with a radiopharmaceutical therapy dosage will be placed in a private room with a toilet. It is acceptable for more than one radiopharmaceutical therapy patient to share the same room.

2. The patient's room will be posted with a "Caution, Radioactive Materials" sign visible at the door.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, at one meter, and the entrance to the room. The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these times in the patient's chart. The results of daily surveys will be used to recalculate permitted times.

4. The form, Nursing Instructions for Patients Treated with Radiopharmaceuticals will be completed immediately after administration of the treatment dose. A copy will be posted in the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in Chapter 1200-2-5-.60 of "State Regulations for Protection Against Radiation."

6. All linens will be surveyed for contamination before being removed from the patient's room and will, if necessary, be held for decay.

7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer (or his designate), checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

8. Non-disposable items used for these patients will be held in plastic bags in the patient's room, and checked for contamination by the Radiation Safety Officer or his designate. Items may be returned for normal use, held for decay or decontaminated, as appropriate.

9. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination (and decontaminated if necessary) and all radioactive waste and waste containers will be removed.

10. Nursing Instructions

    A. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restriction may be noted on the precautions sheet in the patient's chart. Nurses should read these instruction before administering to the patients. Call the Nuclear Medicine Department if you have any questions about the care of these patients.

    B. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precautions sheet in the patient's chart.

    C. Patients must remain in bed while visitors are in the room and visitors should remain at least three feet from the patient.

    D. Radioactive patients are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.

E. No visitor or attendant who is pregnant will be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors will be asked whether they are pregnant.

F. Attending personnel must wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash gloves before removing, and then wash hands. The gloves must be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

G. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Nuclear Medicine Department for proper disposal of the contents of the designated waste container.

H. All clothes and bed linens used by the patient should be placed in the laundry bag provided and left in the patient's room to be surveyed by a member of the Nuclear Medicine Department.

I. All non-disposable items should be placed in a plastic bag and left in the patient's room to be checked by a member of the Nuclear Medicine Department.

J. Surgical dressings should be changed only as directed by physician, Gold 198 leaking from a puncture wound will stain the dressing dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Nuclear Medicine Department. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

K. For Iodine 131 patients:

(1) Disposable plates, cups, and eating utensils will be used by patients who are treated with Iodine 131.

(2) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and/or floor. In any such situations of if radioactive urine and/or feces is spilled, call the Nuclear Medicine Department, Ext. ____. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(3) The same toilet should be used by the patient at all times and it should be well flushed (3 times). If the patient is bedridden, a separate urinal or bedpan should be provided. The urinal or bedpan should be slushed several times with hot soapy water.

L. Utmost precautions must be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Nuclear Medicine Department.

M. If a nurse, attendant, or anyone else knows or suspects that his skin or clothing, including shoes, is contaminated, notify the Nuclear Medicine Department immediately. This person should remain in the patient's room and not walk about the hospital. If the hands become contaminated, wash immediately with soap and water.

N. If a therapy patient should need emergency surgery or should die, notify the Nuclear Medicine Department immediately.

O. When the patient is discharged, call the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

Date: _____

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH RADIOPHARMACEUTICALS

Patient's Name: _____
Room No. _____ Physician's Name: _____
Radioisotope Administered: _____
Date and Time of Administration: _____
Dose Received: _____ Method of Administration: _____

Exposure Rates in mr/hr

Date	**Patient Bedside**	**Room Entrance**

(Comply with all checked items)

_____1. Visiting time permitted:
_____2. Visitors must remain _____ from patient.
_____3. Patient may not leave room.
_____4. Visitors under 18 are not permitted.
_____5. Pregnant visitors are not permitted.
_____6. Personnel monitoring badges must be worn.
_____7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.
_____8. Nursing instructions in patient's chart.
_____9. Patient's door is posted with "Caution-Radioactive Materials."
_____10. Disposable gloves must be worn while attending patient.
_____11. Patient must use disposable utensils.
_____12. All items must remain in room until approved for removal by the Radiation Safety Officer or his/her designee.
_____13. Smoking is not permitted.
_____14. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his/her designee.
_____15. Other instructions _____

In case of an emergency contact:

RSO

Name On-duty/Off-duty Telephone Numbers

APPENDIX K

PROCEDURES FOR HOSPITALIZATION OF BRACHYTHERAPY PATIENTS (GROUP VI)

1. All in-patients treated with brachytherapy sources will be placed in a private room with toilet. It is acceptable for more than one brachytherapy patient to share the same room.

2. The patient's room will be properly posted with a Caution – Radioactive Materials sign visible at the door.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, one meter away, and at the entrance to the room. The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these times in the patient's chart.

4. The form, Nursing Instructions for Patients Treated with Brachytherapy Sources, will be completed immediately after sources are implanted and placed in the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in Rule 1200-2-5-.60 of "State Regulations for Protection Against Radiation."

6. Nurses caring for brachytherapy patients will be assigned personnel monitoring badges unless a determination has been made that they are not likely to exceed 10% of the applicable limits in SRPAR 1200-2-5.

7. At the conclusion of treatment, a survey will be performed to ensure that all temporary sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time all-radiation signs will be removed and all personnel monitoring badges assigned to nurses will be collected.

8. Instruction to Nurses

   A. Special restrictions will be noted on the precaution sheet in the patient's chart. Nurses will read these instructions before administering to the patient. Call the Radiation Therapy Department if you have any questions about the care of these patients.

   B. Nurses will spend only the minimum necessary time near a patient for routine nursing care, but must obtain and wear a personnel monitoring badge if required.

   C. When a nurse receives an assignment to a therapy patient, a personnel monitoring badge will be obtained immediately from the Radiation Therapy Department. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.

   D. Pregnant nurses should not be assigned to the personal care of these patients.

   E. Never touch needles, capsules, seeds, or containers holding brachytherapy sources. If a source becomes dislodged use long forceps and put it in the corner of the room or in the shielded container provided; contact the Radiation Therapy Department at once.

F. Bed bath given by the nurse will be omitted while the sources are in place.

G. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary, unless orders to the contrary have been written.

H. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist, and MAY NOT BE DISCARDED until directed by the radiologist. Dressings will be kept in a basin until checked by the radiologist or member of the Radiation Therapy Department.

Special orders will be written for oral hygiene for patients with oral implants.

I. No special precautions are needed for sputum, urine, vomitus, stools, dishes, Instruments, utensils, or bedding unless specifically ordered.

J. These patients must stay in bed unless orders to the contrary are written.

K. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precaution sheet in the patient's chart.

L. Visitors should sit at least three feet from the patient and should remain no longer than the times specified on the form posted on the patient's door and in his chart.

M. No visitor or attendant who is pregnant will be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors will be asked whether they are pregnant.

N. Emergency Procedures

(1) If an implanted source becomes loose or separated from the patient, or

(2) If the patient dies, or

(3) It the patient requires emergency surgery, immediately call

_____.

Phone No.
(Days)_____(Nights)_____.

O. At the conclusion of treatment, call the Radiation Safety Officer and request that the patient and room be surveyed to be sure all radioactive sources have been removed.

Date: _____

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH BRACHYTHERAPY SOURCES

Patient's Name: _____
Room No. _____ Physician's Name: _____
Isotope and Activity: _____
Date and Time of Administration: _____
Date and Time sources are to be removed: _____ Isotope: _____

Exposure Rates in mr/hr

Date	**Patient's Bedside**	**Room Entrance**

(Comply with all checked items)

_____1. Wear personnel monitoring badge.
_____2. Wear pocket chambers for supplementary personnel monitoring of individual tasks.
_____3. Wear rubber gloves.
_____4. Nursing instructions in patient's chart.
_____5. Patient's door posted with "Caution-Radioactive Materials."
_____6. Place laundry in linen bag and save.
_____7. Housekeeping may not enter the room.
_____8. Visiting time permitted: _____
_____9. Visitors must remain _____from patient.
_____10. Patient may not leave the room.
_____11. Patient may not have visitors.
_____12. Patient may not have pregnant visitors.
_____13. Patient may not have visitors under 18 years of age.
_____14. Patient must have a private room.
_____15. A dismissal survey must be performed before the patient is discharged.
_____16. Other instructions _____

In case of an emergency contact:

RSO

Name On-duty/Off-duty Telephone Numbers

APPENDIX L

PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., XENON 133)

Required information for the use of radioactive gases (e.g., Xenon 133):

1. Submit a diagram of the area(s) in which you plan to use and store Xenon 133.

2. Confirm that negative pressure will be maintained in all areas where Xenon 133 is used, and that the negative pressure will be verified annually.

3. Confirm that there will be a dedicated exhaust vented directly to the atmosphere with no recirculation of air by the system.

4. Submit calculations for air concentrations of Xenon 133 in Restricted and Unrestricted Areas.

   The following procedures may be used to calculate the air concentration of Xenon 133 in restricted areas:

   a. Estimate the maximum amount of activity to be used per week (A).

   b. Estimate the fraction of Xenon 133 that is lost during use and storage (f). This fractional loss must include ALL sources of loss, e.g., during patient administration, storage, and disposal.

   c. Determine the measured airflow rate in the area(s) of interest, and calculate the volume of air available per week for dilution of the Xenon 133 (V).

   d. Calculate the concentration (C) for the restricted area(s) where

$$C = \frac{A \times f}{V}$$

   SRPAR 1200-2-5-.51 requires that C be equal to or less than 1×10^{-4} µCi/ml.

   The following procedure may be used to estimate the concentrations of Xenon 133 in effluents to unrestricted areas.

   a. Estimate the maximum amount of Xenon 133 to be released per year (A).

   b. Estimate the fraction of Xenon 133 to be released per year (f). This should include all anticipated losses during administration, storage, and disposal.

   c. Determine the measured airflow rate of the exhaust system and calculate the airflow quantity per year (V).

   d. Calculate the Concentrations (C) for unrestricted areas where:

$$C = \frac{A \times f}{V}$$

   SRPAR 1200-2-5-.61 requires that C be equal to or less than 5×10^{-7} µCi/ml.

5. Describe the emergency procedures to be used in case of accidental release of Xenon 133. This should include such considerations as temporary evacuation of the area or increasing the ventilation of the area and submit a calculation that's shows Restricted Area concentrations are acceptable for reentry into the room. An acceptable formula is:

   $$\text{Evacuation time } (t) = \frac{-V}{Q} \times \ln(C \times V/A)$$

   V = volume of air in milliliters
   Q = total room air exhaust in milliliters per minute
   C = maximum permissible air concentrations in restricted and unrestricted areas
   A = highest activity of gas in a single container, in microcuries

6. Confirm that you will use charcoal traps or other absorbing medium in your exhaust ventilation system.

7. Confirm that you will ensure collection and trapping devices are performing according to specification, both initially and on a continuing basis (at least monthly).

USEFUL CONVERSIONS		
1 mCi	=	10^3 µCi
1 ft^3	=	2.832 x 10^{-2} m^3 = 2.832 x 10^4 ml
1 ft^3/min	=	1.699 x 10^6 ml/hr
	=	6.797 x 10^7 ml/40-hr week
	=	1.484 x 10^{10} ml/yr
1 week	=	168 hrs

APPENDIX M

PROCEDURES FOR THE USE OF FLUORINE 18 [FDG]

The following information should be submitted by licensees requesting Fluorine 18 [FDG]:

1. Please confirm that F^{18}[FDG] will be used in accordance with all provisions of the package insert shipped with the radiopharmaceutical.

2. Please submit your procedures and a description of where and how F^{18}[FDG] will be stored and shielded at your facility with respect to its higher energies (and yields) and its large activities.

3. Confirm that F^{18}[FDG] will only be received during working hours or that the courier has access to the hot lab.

4. Submit a description of the shielding provided when using and administering F^{18}[FDG] that will show your compliance with ALARA principles and 1200-2-5.-60 of "State Regulations for Protection Against Radiation."

APPENDIX N

WASTE DISPOSAL PROCEDURES

1. Decay-in -Storage

A licensee may hold radioactive material with a half-life of 120 days or less for decay-in-storage for disposal without regard to its radioactivity. The radioactive material shall be monitored in a low background area (less than 0.05 mr/hr) at the container surface to determine that the radioactivity cannot be distinguished from the background level with an appropriate radiation detection instrument set on its most sensitive scale with no interposed shielding. All radiation labels shall be obliterated or removed except for those that are within containers that will be treated as biomedical waste after release by the licensee. Records of each disposal shall be maintained.

2. Return of Licensed Material to Authorized Recipients

Licensed material including used Mo99/TC99m generators may be returned to the manufacturer or authorized recipient in accordance with DOT regulations. A DOT 7A Specification package or strong, tight package shall be assembled in accordance with the manufacturer's instructions, if applicable. Dose rate and removable contamination surveys shall be performed. Proper labels and shipping papers shall be prepared, if applicable. Records of transfer shall be maintained.

3. Liquid Waste

License liquid waste may be disposed of by release into the sanitary sewerage in accordance with SRPAR 1200-2-5-.122.

APPENDIX O

RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS ADMINISTERED RADIOACTIVE MATERIALS

A. INTRODUCTION

A licensee may authorize release from its control any patient administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released patient is not likely to exceed 5 millisieverts (0.5 rem). In this appendix, the individual or human research subject to whom the radioactive material has been administered is called the patient.

This appendix provides guidance on determining when the licensee may authorize the release of a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material, when instructions to the patient are required, and when records are required to be generated and maintained. Activities for commonly used radionuclides and their corresponding dose rate with which a patient may be released are listed.

This appendix is adopted from U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.39 dated April 1997.

B. DIVISION OF RADIOLOGICAL HEALTH (DRH) POSITION

1. RELEASE CRITERIA

Licensees should use one of the following options to release a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material in accordance with regulatory requirements.

1.1 Release of Patients Based on Administered Activity

Licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table 1. The activities in Table 1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual using conservative assumptions of (1) administered activity, (2) physical half-life, (3) occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day, and, for conservatism, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day, and (4) no shielding by tissue. The total effective dose equivalent is approximately equal to external dose because the internal dose is a small fraction of the external dose (see Section B.3, "Internal Dose," of Attachment 3). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child as discussed in DRH Position 3.2, "Records of Instructions for Breast-Feeding Patients." The licensee may demonstrate compliance by maintaining records of administered activity.

If the activity administered exceeds the activity in Column 1 of Table 1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table 1. In this case, a record is required because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table 1 were calculated using either Equation 2 or 3 of ATTACHMENT 2, depending on the physical half-life of the radionuclide.

If a radionuclide not listed in Table 1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for inspection, a calculation of the release activity that corresponds to the dose limit of 5 millisieverts (0.5 rem). Equation 2 or 3 may be used, as appropriate, to calculate the activity Q corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table 1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in a patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table 1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in DRH Positions 2.2 and 2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required.

1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table 1 provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table 1 for that radionuclide. In this case, a record is required because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table 1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 5 millisievert (0.5 rem) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required. The dose rate at 1 meter may be calculated from Equation 2 or 3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q/10{,}000\ cm^2$.

1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 millisieverts (0.5 rem), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table 1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required.

Attachment 3 contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

2. INSTRUCTIONS

2.1 Activities and Dose rates Requiring Instructions

For some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable after the patients are released.[1] Licensees may use Column 1 of Table 2 to determine the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see DRH Position 2.2, "Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release").

The activities or dose rates in Table 2 may be used for determining when instructions must be given. When patient-specific calculations (as described in Attachment 3) are used, instructions must be provided if the calculation indicates a dose that is greater than 1 millisievert (0.1 rem).

If a radionuclide not listed in Table 2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation 2 or 3, of Attachment 2, may be used.

2.2 Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release

It is required that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation. It is presumed that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient.[1] The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, and if the patient was administered a radiopharmaceutical with an activity above the value stated in Column 1 of Table 3, instructions on discontinuation or on the interruption period for breast-feeding and the consequences of failing to follow the recommendation must be provided. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. Table 3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table 3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table 3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50 per cent of the administered activity is excreted in the breast milk (Ref. 2). The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin (Ref. 3).

2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. However, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable person to contact and that person's telephone number in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided.

2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimize time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

[1]The DRH does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine (Ref. 4.). This pamphlet was prepared jointly by the Society of Nuclear Medicine and the NRC. The pamphlet contains blanks for the physician to fill in the length of time that each instruction should be followed. While this pamphlet was written for the release of patients to whom less than 1,100 megabecquerels (30 millicuries) of Iodine 131 had been administered, the instructions in this pamphlet are still considered to be an acceptable method provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving Iodine 131 is that continued breast-feeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in DRH Position 2.2.

Written instructions to patients who could be breast-feeding an infant or child does not in any way interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

2.3.2 Instructions Regarding Permanent Implants

For patients who have received permanent implants, additional instructions may include the following:

- A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for _____ days.
- Stay at a distance of _____ feet from _____.
- Maintain separate sleeping arrangements.
- Minimize time with children and pregnant women.
- Do not hold or cuddle children.
- Avoid public transportation.
- Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.

If you find a seed or pellet that falls out:

- Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid.
- Place the container with the seed or pellet in a location away from people.
- Notify one of the persons listed in this instruction.

3. RECORDS

3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table 1. However, if the release of the patient is based on a dose calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required. This record should include the patient identifier (in a way that ensures confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information.

(1) For Immediate Release of a Patient Based on a Patient-Specific Calculation:
The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Attachment 3 of this guide) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

(2) For Immediate Release of a Patient Based on Measured Dose Rate:
The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

(3) For Delayed Release of a Patient Based on Radioactive Decay Calculation:
The time of the administration, date and time of release, and the results of the decay calculation.

(4) For Delayed Release of a Patient Based on Measured Dose Rate:
The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients. Records should be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These record-keeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients administered radioactive material.

3.2 Records of Instructions for Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required. Column 2 of Table 3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

4. SUMMARY TABLE

Table 4 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table 1. Activities and Dose Rates for Authorizing Patient Release†

Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6.0	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.20	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

†The activity values were computed based on 5 millisieverts (0.5 rem) total effective dose equivalent.

*If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record because the measurement includes shielding by tissue. See DRH Position 3.1, "Records of Release," for information on records.

**Activity and dose limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

NOTES: The millicurie values were calculated using Equations 2 and 3 and the physical half-life. The gigabecquerel values were calculated based on millicurie values and the conversion factor from millicuries to gigabecquerels. The dose rate values are calculated based on the millicurie values and the exposure rate constants.

In general, values are rounded to two significant figures. However, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492 (Ref. 2).

Table 2. Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117m	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

*The activity values were computed based on 1 millisieverts (0.1 rem) total effective dose equivalent.
**Activity and dose limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

NOTES: The millicurie values were calculated using Equations 2 and 3 and the physical half-life. The gigabecquerel values were calculated based on millicurie values and the conversion factor from millicuries to gigabecquerels. The dose rate values were calculated based on millicurie values and exposure rate constants.

In general, values are rounded to two significant figures. However, values less than 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492 (Ref. 2).

Table 3. Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breast-Feeding an Infant or Child

Radiopharmaceutical	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast-Feeding*
	(MBq)	(mCi)	(MBq)	(mCi)	
I-31 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 mIGB	70	2	400	10	24 hr for 370 MBq (10 mCi) 12 hr for 150 MBq (4 mCi)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.30	60	1.5	
Tc-99m DTPA	1,000	30	6,000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 hr for 150 MBq (4 mCi)
Tc-99m Pertechnetate	100	3	600	15	24 hr for 1,100 MBq (30 mCi) 12 hr for 440 MBq (12 mCi)
Tc-99m DISIDA	1,000	30	6,000	150	
Tc-99m Glucoheptonate	1,000	30	6,000	170	
Tc-99m HAM	400	10	2,000	50	
Tc-99m MIBI	1,000	30	6,000	150	
Tc-99m MDP	1,000	30	6,000	150	
Tc-99m PYP	900	25	4,000	120	
Tc-99m Red Blood Cell In Vivo Labeling	400	10	2,000	50	6 hr for 740 MBq (20 mCi)
Tc-99m Red Blood Cell In Vitro Labeling	1,000	30	6,000	150	
Tc-99m Sulphur Colloid	300	7	1,000	35	6 hr for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1,000	30	6,000	150	
Tc-99m MAG3	1,000	30	6,000	150	
Tc-99m White Blood Cells	100	4	600	15	24 hr for 1,100 MBq (5 mCi) 12 hr for 440 MBq (2 mCi)
Ga-67 Citrate	1	0.04	7	0.2	1 month for 150 MBq (4 mCi) 2 weeks for 50 MBq (1.3 mCi) 1 week for 7 MBq (0.2 mCi)

Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 20 MBq (0.5 mCi)
Tl-201 Chloride	40	1	200	5	2 weeks for 110 MBq (3 mCi)

*The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants would be far below 1 millisievert (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.

NOTES: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (Ref. 2).

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding.

Table 4. Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained

PATIENT GROUP	BASIS FOR RELEASE	CRITERIA FOR RELEASE	INSTRUCTIONS NEEDED?	RELEASE RECORDS REQUIRED?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity $\leq$ Column 1 of Table 1	Yes - if administered activity > Column 1 of Table 2	No
	Retained activity	Retained activity $\leq$ Column 1 of Table 1	Yes - if retained activity > Column 1 of Table 2	Yes
	Measured dose rate	Measured dose rate $\leq$ Column 2 of Table 1	Yes - if dose rate > Column 2 of Table 2	Yes
	Patient-specific calculations	Calculated dose ≤ 5 mSv (0.5 rem)	Yes - if calculated dose > 1 mSv (0.1 rem)	Yes
Patients who are breast-feeding an infant or child	All the above bases for release		Additional instructions required if: Administered activity > Column 1 of Table 3 or Licensee calculated dose from breast-feeding > 1 mSv (0.1 rem) to the infant or child	Records that instructions were provided are required if: Administered activity > Column 2 of Table 3 or Licensee calculated dose from continued breast-feeding > 5 mSv (0.5 rem) to the infant or child

REFERENCES

1. National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides," NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095.)

2. S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Final Report), NRC, February 1997.

3. M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine," in *Pediatric Nuclear Medicine*, Edited by S. Treves, Springer Verlag, New York, 1995.

4. "Guidelines for Patients Receiving Radioiodine Treatment," Society of Nuclear Medicine, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 136 Madison Avenue, New York, New York 10016-6760.

ATTACHMENT 1

Table A-1

Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radionuclide	Half-Life (days)[1]	Exposure Rate Constant[2] (R/mCi-h at 1 cm)		Radionuclide	Half-Life (days)[1]	Exposure Rate Constant[2] (R/mCi-h at 1 cm)
Ag-111	7.45	0.150		Pd-103 implant	16.96	0.86[4]
Au-198	2.696	2.3		Re-186	3.777	0.2
Cr-51	27.704	0.16		Re-188	0.708	0.26
Cu-64	0.529	1.2		Sc-47	3.351	0.56
Cu-67	2.578	0.58		Se-75	119.8	2.0
Ga-67	3.261	0.753		Sm-153	1.946	0.425
I-123	0.55	1.61		Sn-117m	13.61	1.48
I-125	60.14	1.42		Sr-89	50.5	NA[5]
I-125 implant	60.14	1.11[3]		Tc-99m	0.251	0.756
I-131	8.04	2.2		Tl-201	3.044	0.477
In-111	2.83	3.21		Y-90	2.67	NA[5]
Ir-192 implant	74.02	4.59[3]		Yb-169	32.01	1.83
P-32	14.29	NA[5]				

[1]K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, D.C., 1988.

[2]Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, pg. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, February 1997.

[3]R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," Medical Physics, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

[4]A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant itself.

[5]Not applicable (NA) because the release activity is not based on beta emissions.

ATTACHMENT 2

The activities at which patients could be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides" (Ref. 1).

NCRP Report No. 37 uses the following equation to calculate the exposure until time **t** at a distance **r** from the patient:

$$D(t) = \frac{34.6\,\Gamma\,Q_0\,T_p\,(1 - e^{-0.693t/Tp})}{r^2} \qquad \textbf{(Equation 1)}$$

Where D(t) = Accumulated exposure at time t, in roentgens,

34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44),

Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm,

Q_0 = Initial activity of the point source in millicuries, at the time of the release,

T_p = Physical half-life in days,

r = Distance from the point source to the point of interest in centimeters,

t = Exposure time in days.

This guide uses the NCRP equation (Equation 1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1-e^{-0.693t/Tp})$ is set equal to 1.

- It is assumed that 1 roentgen is equal to 10 millisieverts (1 rem).

- The exposure rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in ATTACHMENT 1 of this guide.

- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.

- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation 1 is modified to account for the uptake and retention of the radionuclide by the patient as discussed in Attachment 3.

- For radionuclides with a physical half-life greater then 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25 percent of the dose to total decay (0.25 in Equation 2) at a distance of 1 meter. Selection of 25 percent of the dose to total decay at 1

meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis (Ref. 2) that indicate the dose calculated using an occupancy factor, E, of 25 percent at 1 meter is conservative in most normal situations.

- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25 because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (0.25)}{100\ cm^2} \qquad \textbf{(Equation 2)}$$

For radionuclides with a physical half-life less than or equal to 1 day and if an occupancy factor of 1.0 is used:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (1)}{100\ cm^2} \qquad \textbf{(Equation 3)}$$

Equations 2 and 3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent) relative to the external gamma dose (see Section B.3, "Internal Dose," of Attachment 3). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in DRH Position 1.1, "Release of Patients Based on Administered Activity."

ATTACHMENT 3

PROCEDURES FOR CALCULATING DOSES BASED ON PATIENT-SPECIFIC FACTORS

A licensee may release a patient who has been administered an activity higher than the values listed in column 1 of Table 1 of this regulatory guide if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the potential total effective dose equivalent to any individual would be no greater than 5 millisieverts (0.5 rem).

If the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis of the release is required.

The following equation can be used to calculate doses:

$$D(t) = \frac{34.6\,\Gamma\,Q_0\,T_p\,(1 - e^{-0.693t/T_p})}{r^2} \qquad \textbf{(Equation B-1)}$$

Where $D(t)$ = Accumulated dose to time t, in rems

34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)

Γ = Exposure rate constant for a point source, R/mCi x hr at 1 cm

Q_0 = Initial activity at the start of the time interval

T_p = Physical half-life in days

E = Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient

r = Distance in centimeters. This value is typically 100 cm

t = exposure time in days

B.1 OCCUPANCY FACTOR

B.1.1 Rationale for Occupancy Factors Used To Derive Table 1

In Table 1, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members as well as considerations of normal human behavior (as discussed in the supporting regulatory analysis (Ref. B-1)) suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

An occupancy factor of 0.25 at 1 meter is not considered appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time. Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days. However, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table 1 were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day.

B.1.2 Occupancy Factors To Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are provided to the patient before release. The following occupancy factors, E, at 1 meter, may be used for patient-specific calculations.

- E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.

- E = 0.25 when an effective half-life is greater than 1 day if the patient has been given instructions, such as,
  - Maintain a prudent distance from others for at least the first 2 days,
  - Sleep alone in a room for at least the first night,
  - Do not travel by airplane or mass transportation for at least the first day,
  - Do not travel on a prolonged automobile trip with others for at least the first 2 days,
  - Have sole use of a bathroom for at least the first 2 days,
  - Drink plenty of fluids for at least the first 2 days.

- E = 0.125 when an effective half-life is greater than 1 day if the patient has been given instructions, such as,
  - Follow the instructions for E = 0.25 above,
  - Live alone for at least the first 2 days,
  - Have few visits by family or friends for at least the first 2 days.

- In a two-component model (e.g., uptake of Iodine 131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to one day but is greater than one day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 2,220 megabecquerels (60 millicuries) of Iodine 131. The patient has been provided with instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay ($t = \infty$) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ E}{r^2}$$

Since the patient has been provided with instructions for reducing exposure as recommended for an occupancy factor of E = 0.125, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6\ (2.2\ R \bullet cm^2/mCi \bullet hr)\ (60\ mCi)\ (8.04\ d)\ (0.125)}{(100\ cm)^2}$$

$$D(\infty) = 4.59\ \text{millisieverts}\ (0.459\ \text{rem})$$

Since the dose is less than 5 millisieverts (0.5 rem), the patient may be released, but it is required that instructions be given to the patient on maintaining doses to others as low as is reasonably achievable. A record of the calculation must be maintained because an occupancy factor less than 0.25 at 1 meter was used.

B.2 EFFECTIVE HALF-LIFE

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in this appendix. The effective half-life is defined as:

$$T_{eff} = \frac{T_b \times T_b}{T_b + T_b} \qquad \textbf{(Equation B-2)}$$

Where T_b = biological half-life of the radionuclide

T_p = physical half-life of the radionuclide.

The behavior of Iodine 131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F_1 and F_2, respectively) can be calculated with the following equations.

$$T_{1eff} = \frac{T_{b1} \times T_b}{T_{b1} + T_b} \qquad \textbf{(Equation B-3)}$$

$$T_{2eff} = \frac{T_{b2} \times T_b}{T_{b2} + T_b} \qquad \textbf{(Equation B-4)}$$

Where T_{b1} = biological half-life for extrathyroidal iodide

T_{b2} = biological half-life of iodide following uptake by the thyroid

T_p = physical half-life of Iodine 131.

However, simple exponential excretion models do not account for (a) the time for the Iodine 131 to be absorbed from the stomach to the blood and (b) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this guide makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80 percent of the Iodine 131 administered is removed from the body at a rate determined only by the physical half-life of Iodine 131.

Thus, an equation to calculate the dose from a patient administered Iodine 131 may have three components. The first component is the dose for the first 8 hours (0.33 day) after administration. This component comes directly from Equation B-1 using the physical half-life and a factor of 80 percent. The second component is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at t = 8 hours based on the physical half-life of Iodine 131. The second exponential factor represents the activity from t = 8 hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B-5.

Equation B-5:

$$D(\infty) = \frac{34.6\,\Gamma\,Q_0}{(100\text{ cm})^2}\left\{E_1T_p\,(0.8)\,(1 - e^{-0.693(0.33)/Tp}) + e^{-0.693(0.33)/Tp}\,E_2F_1T_{1eff} + e^{-0.693(0.33)/Tp}\,E_2F_2T_{2eff}\right\}$$

F_1 = Extrathyroidal uptake fraction

F_2 = Thyroidal uptake fraction

E_1 = Occupancy factor for the first 8 hours

E_2 = Occupancy factor from 8 hours to total decay.

All of the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1, T_{1eff}, F_2, and T_{2eff} are shown in Table B-1 for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release is described in DRH Position 3.1 of this appendix.

Example 2. Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 7,400 megabecquerels (200 millicuries) of Iodine 131 for the treatment of thyroid remnants and metastases.

Solution: In this example, we will calculate the dose by using Equation B-5 to account for the elimination of Iodine 131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from Table A-1 of Attachment 1. The uptake fractions and effective half-lives are from Table B-1. An occupancy factor, E, of 0.75 at 1 meter will be used for the first component because the time period under consideration is less than 1 day. However, for the second and third components, an occupancy factor of 0.25 will be used because (1) the effective half-life associated with the dominant component is greater than 1 day and (2) patient-specific questions were provided to the patient to justify the occupancy factor (see Section B.1.2, "Occupancy Factors To Consider for Patient-Specific Calculations," of this Attachment 3).

Table B-1. Uptake Fractions and Effective Half-Lives for Iodine 131 Treatments				
Medical Condition	**Extrathyroidal Component**		**Thyroidal Component**	
	Uptake Fraction F_1	**Effective Half-Life T_{1eff} (day)**	**Uptake Fraction F_2**	**Effective Half-Life Fraction $F_2 T_{2eff}$ (day)**
Hyperthyroidism	**0.20**[1]	**0.32**[2]	**0.80**[1]	**5.2**[1]
Post-thyroidectomy for Thyroid Cancer	**0.95**[3]	**0.32**[2]	**0.05**[3]	**7.3**[2]

[1] M.G. Stabin et al., "Radiation Dosimetry for the Adult Female and Fetus from Iodine 131 Administration in Hyperthyroidism," *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this referenced document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75 percent of the data points shown in Figure 1 of this *Journal of Nuclear Medicine* document.

[2] International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in this ICRP document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid) as suggested in this ICRP document.

[3] The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., NRC medical visiting fellow, as an upper limit post-thyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is

$$D(\infty) = \frac{34.6\ (2.2)\ (200)}{(100\ \text{cm})^2}\ \{(0.75)\ (8.04)\ (0.8)\ (1 - e^{-0.693(0.33)/8.04})$$

$$+\ e^{-0.693(0.33)/8.04}\ (0.25)\ (0.95)\ (0.32)$$

$$+\ e^{-0.693(0.33)/8.04}\ (0.25)\ (0.05)\ (7.3)\}$$

$$D(\infty) = 4.53\ \text{millisieverts (0.453 rem)}$$

Therefore, thyroid cancer patients administered 7,400 megabecquerels (200 millicuries) of Iodine 131 or less would not have to remain under licensee control and could be released, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose is not greater than 5 millisieverts (0.5 rem).

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3. Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 2,035 megabecquerels (55 millicuries) of Iodine 131 for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, we will again calculate the dose using Equation B-5, Table A-1, and Table B-1 to account for the elimination of Iodine 131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E, of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2, "Occupancy Factors To Consider for Patient-Specific Calculations").

Substituting the appropriate values into Equation B-5, the dose to total decay is

$$D(\infty) = \frac{34.6\ (2.2)\ (55)}{(100\ cm)^2}\ \{(0.75)\ (8.04)\ (0.8)\ (1 - e^{-0.693(0.33)/8.04})$$

$$+\ e^{-0.693(0.33)./8.04}\ (0.25)\ (0.20)\ (0.32)$$

$$+\ e^{-0.693(0.33)/8.04}\ (0.25)\ (0.80)\ (5.2)\}$$

$$D(\infty) = 4.86\ \text{millisieverts}\ (0.486\ \text{rem})$$

Therefore, hyperthyroid patients administered 2,035 megabecquerels (55 millicuries) of Iodine 131 would not have to remain under licensee control and could be released when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction, $F_2 = 0.8$, is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 INTERNAL DOSE

For some radionuclides, such as Iodine 131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

$$D_i = Q\ (10^{-5})(DCF) \qquad \text{(Equation B-6)}$$

Where D_i = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rems

Q = Activity administered to the patient in millicuries

10^{-5} = Assumed fractional intake

DCF = Dose conversion factor to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in Reference B-3 for cases of worker

intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply for cases of intake by an individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered Iodine 131 indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4. Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient who has been administered 1,110 megabecquerels (33 millicuries) of Iodine 131. The ingestion pathway was selected since it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rems/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.17 \text{ mSv } (0.017 \text{ rem})$$

In this case, the external dose to the other person would be no greater than 5 millisieverts (0.5 rem), while the internal dose would be about 0.17 millisievert (0.017 rem). Thus, the internal dose is about 3 percent of the external gamma dose. Internal doses may be ignored in the calculations if they are likely to be less than 10 percent of the external dose since the internal dose would be significantly less than the uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from radionuclide Therapy Patients" (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely."

For additional discussion on the subject, see Reference B-1.

REFERENCES FOR ATTACHMENT 3

B-1. S. Schneider and S.A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," USNRC, NUREG-1492, February 1997.

B-2. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion*, Federal Guidance Report No. 11, U. S. Environmental Protection Agency, Washington, DC, 1988.

B-3. A. Brodsky, "Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10-6 a Magic Number in Health Physics?')," *Health Physics*, Volume 39, Number 6, 1980.

B-4. R.C.T. Buchanan and J.M. Brindle, "Radioiodine Therapy to Out-Patients – The Contamination Hazard," *British Journal of Radiology*, Volume 43, 1970.

B-5. A.P. Jacobson, P.A. Plato, and D. Toeroek, "Contamination of the Home Environment by Patients Treated with Iodine 131," *American Journal of Public Health*, Volume 68, Number 3, 1978.

B-6. National Council on Radiation Protection and Measurements, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients," Commentary No. 11, February 28, 1995.

APPENDIX P

INTRAVASCULAR BRACHYTHERAPY PROCEDURES

The following are points to cover when submitting a request for intravascular brachytherapy devices that have been approved for clinical use.

1. Commit to limit the use of these systems to treat intravascular brachytherapy.

2. Commit to vendor training for the treatment team.

3. Confirm that the treatment team will be composed of, at a minimum, an interventional cardiologist, authorized user radiation therapist and medical physicist.

4. Confirm that all procedures will be conducted under the supervision of the authorized user radiation therapist, who will consult with the interventional cardiologist and authorized medical physicist prior to initiating treatment. Also, confirm that the authorized user or the medical physicist will physically present during all treatments. It is acceptable that a designate of the medical physicist under their supervision may be present as a substitute. All shall have completed vendor training. Physical presence for this purpose is defined as within audible range of normal human speech.

5. Verify that an independent verification measurement be made by the licensee before treatment of the first patient with that specific source.

6. Commit to preparing written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures. At a minimum, equipment should consist of a shielded source container and long handled forceps.

7. Describe how the device will be locked in storage when not in use to prevent tampering or removal by unauthorized personnel.

8. The licensee shall survey the patient and the IVB treatment catheter immediately following source retraction or removal to confirm complete retraction of the source(s).

9. If you wish to perform “source-stepping”, establish the appropriate procedures in writing.

Novoste BetaCath System specific information to be submitted:

1. Commit to the use introducer sheath (or equivalent) to prevent source transport blockages during treatment, which could lead to misadministration, unless such use is contraindicated for an individual patient.

2. Commit to the use of the dual syringe system to avoid misadministrations due to premature depletion of the source transport fluid, unless such use is contraindicated for an individual patient.

3. Commit to storing the BetaCath device in its lead-lined storage container when not in use.

4. Confirm that the BetaCath device will be inspected and service at intervals recommended by the manufacturer. Verify that service and maintenance shall only be performed by the manufacturer, or persons specifically licensed by the NRC or an Agreement State to perform such services.

5. Provide information concerning the location of the storage container. Confirm the storage area is locked and in a secure location.

Guidant Galileo IVB System specific information to be submitted:

1. Provide information concerning the location of the delivery device, source assembly, and the key control for the console key. Confirm the storage area is locked and in a secure location.

2. Confirm that the Galileo device will be inspected and service at intervals recommended by the manufacturer. Verify that service and maintenance shall only be performed by the manufacturer, or persons specifically licensed by the NRC or an Agreement State to perform such services.

3. Confirm that daily checks shall be performed (prior to patient treatment) in accordance with the manufacturer's instructions to include: console operational checks, indicator lamps, source status indicators, visual inspection of the integrity of the source centering catheter and connectors, and source positioning accuracy.

4. Confirm that the following tests shall be performed at each source exchange (prior to patient treatment): source uniformity via radiograph, source positioning accuracy within ±1 mm, battery backup for emergency source retraction upon power failure, source transmit time to meet manufacturer's specifications, and timer accuracy and linearity to meet manufacturer's specifications.

Cordis Checkmate IVB System specific information to be submitted:

1. Submit calculations and/or measurements demonstrating compliance with shielding requirements and "State Regulations for Protection Against Radiation."

APPENDIX Q

HIGH DOSE RATE AFTERLOADER PROCEDURES

Provide a facility diagram that shows the use and storage area for the afterloader device. Provide a description of the facility shielding.

Submit a description of the following:

1. In-room radiation monitor to determine that radiation levels have returned to ambient levels.

   (An acceptable system would be a beam-on radiation monitor with a visible flashing light that is permanently mounted in each therapy room. It shall be equipped with an emergency power supply separate from the power supply of the therapy unit).

2. System for continuous observation of the patient.

   (If a shielded window is to be used provide its thickness, density, and material of construction. If a TV or other electronic system is to be used specify the back-up system to be used in case of failure, or commit to the suspension of treatments until repair.

3. Communication with the patient.

   (An open microphone is acceptable)

4. Interlock system that will include at a minimum:

   A. Each door leading into the treatment room will be provided with an interlock to control the on-off mechanism of the therapy unit.

   B. The interlock must cause the source to move to the off position or shield the source(s) if the door to the treatment room is opened when the source is exposed.

   C. The interlock system will prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed.

   D. The interlock system shall be constructed so as to only allow one source of radiation to be used at any one time.

   E. The interlock must be wired so that the source(s) cannot be returned to the on position after interlock interruption until the treatment room door is closed and the system is reset at the control panel.

5. Method to control console keys so that they remain inaccessible to unauthorized personnel.

Emergency written procedures that a minimum will do the following:

1. When the procedures are to be implemented, such as any circumstance under which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.
2. The actions specified for emergency source recovery or shielding which primarily consider minimizing exposure to the patient and healthcare personnel while maximizing safety of the patient.

3. The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures must clearly specify which steps are to be taken under different scenarios. The procedure must specify situations in which surgical intervention may be necessary and the steps that should be taken in the event that surgical intervention is required.

4. Identification of the location of emergency source recovery equipment and specification of what equipment may be necessary for the various scenarios described in the procedure. At a minimum, emergency equipment must include shielded storage containers, remote-handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient.

5. Giving first consideration to minimizing the exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position).

6. Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.

7. Specifying who is to be notified.

8. Requirements to restrict (lock, if necessary) and post the treatment room with appropriate warning signs as soon as the patient and staff are out of the treatment room.

Unit operating procedures that at a minimum will do the following:

1. Steps to ensure that the device, console, and treatment room will be secured when unattended.

2. The patient will be alone in the treatment room, unless contraindicated, during HDR therapy.

3. Nursing personnel follow the authorized users' and RSO's specific instructions regarding care to be provided to a patient during the treatment process. If a treatment is to be conducted over a period of several hours and direct patient care will be required, such instructions should be provided to the nursing staff in writing.

4. Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system should have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and should be relabeled) in accordance with the manufacturer's instructions.

5. A treatment procedure will not be conducted if a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded container.

6. If the interlock system malfunctions, the device will be locked in the off position and not used, except as may necessary for repair of replacement of the interlock system, until the interlock system is shown to be functioning properly.

7. If a radiation monitor used to indicate the source position is found to be either inoperable or intermittently inoperable, the device will be locked in the off position and not used, except as may be necessary for repair or replacement, until the radiation monitor is shown to be functioning properly.

APPENDIX R

PROCEDURES FOR HOSPITALIZED PATIENTS TREATED WITH GROUP VI LOW ENERGY SOURCES (Pd-103/I-125)

1. All in-patients treated with brachytherapy sources will be placed in a private room with toilet. It is acceptable for more than one brachytherapy patient to share the same room.

2. The patient's room will be properly posted with a "Caution, Radioactive Material" sign visible at the door.

3. Surveys of the patient's room will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, three feet away and at the entrance to the room. The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these times in the patient's chart.

4. The form, Nursing Instructions for Patients Treated with Low Energy Brachytherapy Sources, will be completed immediately after sources are implanted and placed in the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in Rule 1200-2-5-.60 of "State Regulations for Protection Against Radiation."

6. Nurses caring for brachytherapy patients will be assigned personnel monitoring devices unless a determination is made that they are not likely to exceed 10% of the applicable limits in SRPAR 1200-2-5. This documentation will be maintained for inspection by this Department.

7. No pregnant nursing personnel will take care of these patients.

8. No visitors under the age of 18 or pregnant.

9. Instruction to Nurses

    A. Special restrictions will be noted on the precaution sheet in the patient's chart. Nurses will read these instructions before administering to the patient. Call the Radiation Therapy Department if you have any questions about the care of these patients.

    B. Nurses will spend only the minimum necessary time near a patient for routine nursing care, but must obtain and wear personnel monitoring devices unless otherwise determined. If it is determined a nurse will wear personnel monitoring devices, they will be obtained immediately from the Radiation Therapy Department. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.

    C. Some of the sources may pass through the foley catheter into the bag of urine so it will need to be surveyed. If seeds are found in the patient urine, use long forceps and place it in the shielded container provided; contact the Radiation Therapy Department at once.

    D. Visitors should remain no longer than the times specified on the form posted on the patient's door and in his chart.

    E. No visitors under the age of 18 or pregnant.

F. Emergency Procedures

(1) If an implanted source passes through the foley catheter into the bag of urine, or

(2) If the patient dies, or

(3) It the patient requires emergency surgery, immediately call

_____.

Phone No.
(Days)_____(Nights)_____.

Date: _____

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH LOW ENERGY BRACHYTHERAPY SOURCES

Patient's Name: _____
Room No. _____ Physician's Name: _____
Isotope and Activity: _____
Date and Time of Administration: _____

Exposure Rates in mr/hr

Date	**Patient Bedside**	**Room Entrance**

(Comply with all checked items)

_____1. Wear personnel monitoring devices if applicable.
_____2. Patient may not have pregnant visitors.
_____3. Patient may not have visitors under 18 years of age.
_____4. Place laundry in linen bag and save.
_____5. Visitors must remain _____from patient.
_____6. Patient must have a private room.
_____7. A room closeout survey performed after the patient is discharged.
_____8. Other instructions _____

In case of an emergency contact:

RSO

Name	On-duty/Off-duty	Telephone Numbers

APPENDIX S

MOBILE MEDICAL SERVICES

1. In general, there are two types of mobile medical services in which radioactive material is used. One type is transportation and use within a transport vehicle. A second type is transportation to a client's facility and use within that facility. The provider of these mobile services will need to obtain a radioactive material license for use within Tennessee. Licensed operations shall be performed under the supervision of an authorized user physician who takes responsibility for the client locations.

2. The licensee shall obtain a letter signed by the management of each of its clients for which services are rendered. The letter will permit the use of licensed material at the client's address and will clearly delineate the authority and responsibility of each entity. Confirm that there is an emergency physician in the location or site. A copy of this letter shall be submitted with the license application or amendment.

3. The licensee shall ensure that all licensed material including radiopharmaceuticals, sealed sources, and all associated radioactive wastes shall be removed before leaving the client's address.

4. If the licensee will maintain a base location in Tennessee, specify its location. Provide a description and diagram of this facility and associated equipment including adjacent areas. Describe how the facility will be secured from unauthorized access. If the base location is to be in a mobile van, it shall be in secured off-street parking under licensee control not on a public right-of-way. Surveys shall be performed as necessary to show that dose to the public radiation levels do not exceed 2 millirem in any one hour and 100 millirem in a year.

5. The licensee will need to provide a list of the name and address of each client for which licensed activities will be performed. A diagram of the location of use at the client facility including adjacent areas shall be submitted. Instruments used to measure the activity of licensed material and transported imaging cameras shall be checked for proper operation at each client's address or on each day of use, whichever is more frequent. Licensed material may be delivered to a van only if licensed personnel are present, or to a client facility if licensed.

6. The licensee shall develop emergency procedures to be implemented in the case of an accident. They shall contain the following:

   A. 24-hour emergency contact telephone number for the licensee's responsible individual(s) and The Tennessee Emergency Management Agency at 1-800-262-3300 or 615-741-0001.

   B. Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazard exists.

   C. Procedures for retrieving and securing any radioactive material.

   D. Decontamination procedures.

   E. The provision for a calibrated, operational survey meter to be maintained in the cab of the transporting vehicle.